

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Susan Slaugenhauspt et al.

Group Art Unit: 1634

Serial No.: 10/041,856

Examiner: Carla Myers

Filed: January 7, 2002

Confirmation No.: 5418

For: Gene For Identifying Individuals With Familial Dysautonomia

DECLARATION OF THE INVENTORS UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Susan A. Slaugenhauspt and James F. Gusella, citizens of the United States of America residing at 10 Quail Run, Hingham, MA 02043 and 7 Woodstock Drive, Framingham, Massachusetts 01701, respectively, so hereby declare and state that:

1. We are the co-inventors of the invention that is disclosed and claimed in the above-identified application, Serial No. 10/041,856, filed January 7, 2002, which claims priority to U.S. Application Serial No. 60/260,080, filed January 6, 2001, now abandoned. The claimed invention relates to mutations associated with Familial Dysautonomia (FD), the detection of which can be used to screen for FD.

2. We are the Susan A. Slaugenhauspt and James F. Gusella named, *inter alia*, as authors on "Tissue-Specific Expression of a Splicing Mutation in the *IKBKAP* Gene Causes Familial

Dysautonomia" published in the American Journal of Human Genetics on January 22, 2001 ("Slaugenhaupt publication"). We are also the Susan A. Slaugenhaupt and James F. Gusella named on Gill et al., GenBank Accession No. AF153419, published on January 2, 2001 ("Gill publication") and Slaugenhaupt et al., GenBank Accession No. AF153419, published on February 27, 2001 ("Slaugenhaupt Genbank publication").

3. The other authors on the Slaugenhaupt publication -- Anat Blumenfeld, Sandra P. Gill, Maire Leyne, James Mull, Math P. Cuajungco, Chistopher B. Liebert, Brian Chadwick, Maria Idelson, Luba Reznick, Christaine M. Robbins, Izabela Makalowska, Michael J. Brownstein, Daniel Krappmann, Claus Scheidereit, Channa Maayan, and Felicia Axelrod -- the other authors on the Gill publication -- Brian Chadwick, Sandra P. Gill, Maire Leyne, James Mull, and Chistopher B. Liebert -- and the other authors on the Slaugenhaupt Genbank publication -- Brian Chadwick, Sandra P. Gill, Maire Leyne, James Mull, and Chistopher B. Liebert -- contributed to the research as follows:

4. Anat Blumenfeld was a postdoctoral fellow in the Gusella laboratory working under the direction of James Gusella and contributed to aspects of the Familial Dysautonomia research described in the Slaugenhaupt publication, but did not make an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application. Anat Blumenfeld also provided patient samples which were also used in the studies carried out in developing the invention. Math P. Cuajungco and Brian Chadwick were postdoctoral fellows in the Slaugenhaupt laboratory working under the direction of Susan Slaugenhaupt on aspects of the research described in the Slaugenhaupt publication, but they did not make an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application.

5. Christopher B. Liebert, Sandra P. Gill, James Mull, and Maire Leyne were Senior Research Technologists in the Slaugenhaus laboratory working under the direction and control of Susan Slaugenhaus and they did not make an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application.

6. Daniel Krappmann and Claus Scheidereit, from the Max-Delbrück-Centrum for Molecular Medicine in Berlin, Germany, provided reagents to us that were described in the Slaugenhaus publication and they did not make an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application.

7. Christiane M. Robbins, Izabela Makalowska, and Michael J. Brownstein from the National Institutes of Health collaborated with the Slaugenhaus laboratory, and, at Susan Slaugenhaus's direction, sequenced samples sent to them by the Slaugenhaus laboratory. These individuals did not make an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application.

8. Maria Idelson and Luba Reznick from the Department of Clinical Biochemistry, and Channa Maayan from the Department of Pediatrics, all of Hadassah University Hospital in Jerusalem, Israel, provided patient samples to us for use in studies carried out in developing the invention under Susan Slaugenhaus's direction. None of these individuals made an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application. Felicia Axelrod, from the Department of Pediatrics at New York University Medical Center in New York also provided patient samples to us for use in the studies carried out in developing the invention, and did not make an inventive contribution to the conception of the subject matter disclosed and claimed in the referenced application.

9. Thus, while Anat Blumenfeld, Sandra P. Gill, Maire Leyne, James Mull, Math P. Cuajungco, Christopher B. Liebert, Brian Chadwick, Maria Idelson, Luba Reznick, Christaine M. Robbins, Izabela Makalowska, Michael J. Brownstein, Daniel Krappmann, Claus Scheidereit, Channa Maayan, and Felicia Axelrod are named as authors of the Slaugenhaupt publication, and Brian Chadwick, Sandra P. Gill, Maire Leyne, James Mull, and Christopher B. Liebert are named as authors on the Gill publication and on the Slaugenhaupt Genbank publication, they did not make an inventive contribution to the subject matter disclosed and claimed in the referenced application and thus are not inventors of the subject matter of the referenced application.

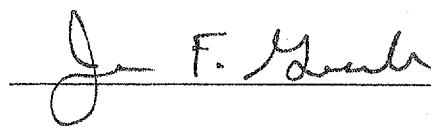
10. We declare further that all statements made in this Declaration of our own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 2-28-07



Susan A. Slaugenhaupt

Date: 2/28/07



James F. Gusella